K123091

510(k) SUMMARY FOR VISIUS WIRELESS COILS 1.5T/3T

(As required by 21 CFR 807.92)

DEC 2 7 2012

1. GENERAL INFORMATION

Establishment:	IMRIS Inc.
Address:	100-1370 Sony Place Winnipeg, Manitoba Canada, R3T 1N5
Registration Number:	3003807210
Contact Person:	Primary Contact: Mr. Sanjay Shah QA and Regulatory Engineer Email: sshah@imris.com Phone: 1-204-480-7070 Fax: 1-204-480-7071
	Secondary Contact: Mr. Daniel Biank Director, Regulatory Affairs Email: dbiank@imris.com Phone: 1-952-358-7046 Fax: 1-204-480-7071
Date of Summary Preparation:	November 23, 2012
Device Name/ Trade Name	VISIUS Wireless Coils, 1.5T VISIUS Wireless Coils, 3T
Classification Name:	Magnetic resonance diagnostic device.
Classification Panel:	Radiology
Classification (CFR section):	21 CFR 892.1000
Class:	Class II
Product Code:	MOS

2. PREDICATE DEVICES

IMRIS 1.5T/3T VISIUS Wireless Coils are substantially equivalent to the IMRIS HC150/HC300 coils.

NAME OF THE DEVICE	510(K) NUMBER	DATE OF CLEARANCE	MANUFACTURER
IMRIS HCI50 (I.5T Head Coil) and HC300 (3T Head Coil)	K103506	Feb 2, 2011	IMRIS Inc.

A.1

3. DEVICE DESCRIPTION

The IMRIS VISIUS Wireless Coil 1.5T is a receive-only three channel flexible phased array coil. The 1.5T upper coil has two elements and the lower coil has one element. The 1.5T VISIUS Wireless Coils is a pair of receive-only phased array coils designed for use with the IMRIS/Siemens MAGNETOM 1.5T MRI system.

The IMRIS VISIUS Wireless Coils, 3T is a receive-only three channel flexible phased array coil. The 3T upper coil is has two elements and the lower coil has one element. The 3T VISIUS Wireless Coils is a pair of receive-only phased array coils designed for use with the IMRIS/Siemens MAGNETOM 3T MRI system.

The IMRIS 1.5T/3T VISIUS Wireless Coils balance surgical requirements with the MRI requirements to provide MR imaging in intra-operative and interventional procedures. The coils are used to acquire MR images of the head and upper C-spine during intra-operative /interventional procedures. The IMRIS 1.5T/3T Disposable Coils can also be used as standard diagnostic head coils for diagnostic examinations.

4. INDICATIONS FOR USE

VISIUS Wireless Coils 1.5T and 3T are intended for use with IMRIS (Siemens MAGNETOM) 1.5T and 3T MRI Systems as an imaging device for clinical procedures.

VISIUS Wireless Coils produce images of the head and upper C-spine internal structures.

When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis and therapy options.

5. COMPARISION TO PREDICATE DEVICES

Characteristic	IMRIS HC 150 / HC 300 Coils	**IMRIS 1.5T/3T VISIUS Wireless Coils**
FDA 510(k) #	K102155	Current Submission
Manufactured by	IMRIS Inc.	IMRIS Inc.
Intended use /Indications for use	IMRIS Flex coils HC150 (1.5T Head coil) and HC300 (3T Head coil) are used in conjunction with respective MR Systems IMRIS 1.5T MAGNETOM and IMRIS 3T MAGNETOM as an imaging device for clinical procedures. IMRIS Flex coils produce images of the human head and upper C-spine internal structures. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis and therapy options.	VISIUS Wireless Coils 1.5T and 3T are intended for use with IMRIS (Siemens MAGNETOM) 1.5T and 3T MRI Systems as an imaging device for clinical procedures. IMRIS VISIUS Wireless Coils produce images of the head and upper C-spine internal structures. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis and therapy options.
Where used	Hospital Diagnostic room / Operating room	Hospital Diagnostic room / Operating room

Anatomical sites	Head and upper C-spine	Head and upper C-spine

6. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE: (807.92 (A) (6))

1.5T/ 3T VISIUS Wireless Coils Characterists

CHARACTERISTIC	HC150	HC300	VISIUS WIRELESS COILS 1.5T	VISIUS WIRELESS COILS 3T	COMPARISION
FDA 510(k) #	K103506	K103506	THIS SUBMISSION	THIS SUBMISSION	
MRI system Compatibility	IMRIS 1.5T MRI system (Siemens MAGNETOM 1.5T MRI scanner)		IMRIS 1.5T MRI system (Siemens MAGNETOM 1.5T MRI scanner)		Same
		IMRIS 3T MRI system (Siemens MAGNETOM 3T MRI scanner)		IMRIS 3T MRI system (Siemens MAGNETOM 3T MRI scanner)	Same
Coil Type	Receive-only eight channel phased array coil	Receive-only eight channel phased array coil	Receive-only three channel phased array coil	Receive-only three channel phased array coil	Same Phase array coil
System connection	The coil plugs into the MRI System	The coil plugs into the MRI System	Inductive Coupling	Inductive Coupling	Different
RF Cable Interface	Interface Cable with Insulated Cable Traps	Interface Cable with Insulated Cable Traps	No Cable	No Cable	Different
Tune and Match	No tune, no match	No tune, no match	No tune, no match	No tune, no match	Same
Safety features	Active and Passive Decoupling	Active and Passive Decoupling	Passive Decoupling	Passive Decoupling	Same
	RF Fuse	RF Fuse	RF Fuse	RF Fuse	Same
Coil Enclosure Material and design	Polyurethane Plastic, Vinyl coated closed cell foam	Polyurethane Plastic, Vinyl coated closed cell foam	Polyethylene EVA with CFMS health care fabric	Polyethylene EVA with CFMS health care fabric	Different
	Flexible	Flexible	Flexible	Flexible	Same
Cleaning and Sterilization	Cleaning	Cleaning	Top Coil: ETO Sterilized Bottom coil: Cleaned	Top Coil: ETO Sterilized Bottom Coil: Cleaned	Different
Reusable	Yes	Yes	Top Coil: No, single use. Bottom Coil: Yes	Top Coil: No, single use. Bottom Coil: Yes	Different

7. SUMMARY OF NON-CLINICAL DATA

Design Verification and Validation Test (Bench Testing)

The IMRIS 1.5T/3T VISIUS Wireless Coils passed the following tests and meets product specifications.

IMRIS has performed a number of V&V tests. The main tests include

- IEC 60601-1 compliance
- IEC 60601-2-33 compliance
- Clinical image comparison
- MRI compatibility test (MR image artifacts test, MR heating test),
- Surface heating (normal and single fault conditions)
- Single fault condition unplugged (passive detuning test)
- Workflow
- The 1.5T/3T VISIUS Wireless Coils Image Non-Uniformity and SNR was measured and is reported in accordance with NEMA MS 9-2008 Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images. The NEMA MS 9-2008 references the ALTERNATE MEASUREMENT PROCEDURE as described in NEMA MS 6-2008
- The sterilization method was validated and performed in accordance with ANSI/AAMI/ISO 11135-1:2007, Sterilization of health care products- Ethylene oxide- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. A sterility assurance level of 10^{-6} has been validated for this product

The IMRIS 1.5T/3T VISIUS Wireless Coils are tested for electrical, mechanical, and flammability hazards. The IMRIS 1.5T/3T VISIUS Wireless Coils complies with voluntary standards (IEC 60601-1, IEC 60601-2-33, and UL 94). The 1.5T/3T VISIUS Wireless Coils provided clinical images which demonstrate the clinical effectiveness of the 1.5T/3T Disposable Craniotomy Coils. The 1.5T/3T VISIUS Wireless Coils are tested for MR image artifacts and surface heating test. The 1.5T/3T VISIUS Wireless Coils SNR and Image non-uniformity are tested according to NEMA standards. The tests outlined above have been executed with acceptable results. Performance data demonstrate safety and effectiveness of the IMRIS 1.5T/3T Disposable Craniotomy Coils.

8. CONCLUSION

The IMRIS 1.5T/3T VISIUS Wireless Coils have the same intended use and indications for use as the predicate devices. Performance data demonstrate safety and effectiveness of the IMRIS 1.5T/3T VISIUS Wireless Coils with the new characteristics.

The IMRIS 1.5T/3T VISIUS Wireless Coils verification/validation results and performance/safety standard results show that the device is safe and effective and substantially equivalent to the currently available predicate device, HC150/HC300 coils.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 27, 2012

Sanjay Shah
IMRIS, Inc
100-1370 Sony Place
Winnipeg, Manitoba
CANADA, R3T 1N5

Re: K123091
Trade/Device Name: VISIUS Wireless Coils, 1.5T, VISIUS Wireless Coils, 3T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: December 7, 2012
Received: December 11, 2012

Dear Mr. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

IMRIS

Indications for Use

510(k) Number (if known): K123091

Device Name: VISIUS Wireless Coils 1.5T / VISIUS Wireless Coils 3T

Indications For Use:

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) K123091